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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,882	07/21/2003	Milton B. Shields	25006.0016U1	6789

23859 7590 10/04/2005

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EXAMINER

DEAK, LESLIE R

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.		Applicant(s)	
	10/624,882		SHIELDS, MILTON B.	
	Examiner		Art Unit	
	Leslie R. Deak		3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10/03, 3/04, 12/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-13, 19-27, 29, and 44-50 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,521,210 to Wong. Wong discloses an eye implant for relieving glaucoma that discloses substantially all the claimed limitations. Wong's implant comprises an elongate body with a forward and back end, sharp leading edge 50, a fusiform cross-sectional shape (see FIG 3B), a shoulder surface 44 with an area of increased width, and channels, slits, or conduits that run through the device with openings at perforations 70 to channel fluid therethrough. (Since the openings are located on the upper surface of the implant, they are arranged at an acute angle from the upper surface.) The device has substantially coplanar upper and lower surfaces, and is made of a semi-rigid biocompatible material that may not be porous and curved to conform to the shape of the eye (see FIG 3B), and further comprises a grooved surface (see column 4, lines 15-55, column 7, lines 50-51, FIGS 3C, 15A). The implant further comprises notches 52, 54, and extends from the anterior chamber to the suprachoroidal space (see column 5, lines 35-55). Wong's device further comprises both planar and grooved surfaces on the upper and lower portions of the implant that are suitable for grasping by a

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surgical tool for insertion into the eye. A recitation with respect to the manner in which a claimed apparatus or component is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations.

3. With regard to applicant's method, Wong discloses the step of making an incision through the sclera, providing the claimed conduit, inserting it into the anterior chamber of the eye (which requires grasping of some sort, since the implant is not capable of self-implantation), maneuvering the back end of the implant into the suprachoroidal space while positioning the shoulder or cross-arm into the correct location, and suturing the incision closed (see column 5, lines 10-60).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-16, 30, 31, 34-41, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,521,210 to Wong in view of US 5,599,330 to Rainin. Wong discloses the device as claimed with the exception of a wicking member to carry fluid through the implant. Rainin discloses a surgical wicking member, disclosing that a tube may comprise a wicking member via capillary

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action in order to remove fluid from a large area for aspiration. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the conduits provided in the Wong implant with capillary tubes, as taught by Rainin, in order to remove fluid from a large surface area for aspiration, as taught by Rainin.

6. Claims 14, 18, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,521,210 to Wong in view of 5,476,445 to Baerveldt et al. Wong discloses the device as claimed with the exception of suture bores and a tube extending from the implant. Baerveldt discloses an ocular implant for glaucoma relief with a generally planar surface adapted to the curvature of the eye, with a conduit that may or may not extend the length of the implant (see FIGS 5, 9a, 9b) connected to a drainage tube 41 that spans the eye to drain excess fluid to the anterior chamber of the eye. The Baerveldt implant further comprises suture bores 74-77 that prevent the migration of the device into the eye socket tissue. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide multiple suture points, including suture bores, to the Wong device to prevent the migration of the device to the eye socket, as taught by Baerveldt. Further, it would have been obvious to one having ordinary skill in the art at the time of invention to add a drainage tube disclosed by Baerveldt to the Wong device in order to span the eye and direct excess fluid to a diverse portion of the eye, as taught by Baerveldt.

7. Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,521,210 to Wong in view of US 5,599,330 to Rainin further in view of

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5,476,445 to Baerveldt et al. It would have been obvious to one having ordinary skill in the art at the time of the invention to provide the implant with the wicking members as disclosed by Wong and Rainin with suture bores as disclosed by Baerveldt in order to provide multiple suture points, including suture bores, to the Wong device to prevent the migration of the device to the eye socket, as taught by Baerveldt.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- a. US 6,142,969 Nigam
 - i. Sutureless implantable glaucoma treatment device


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lfd
26 September 2005


PATRICIA BIANCO
PRIMARY EXAMINER
9/30/05